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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,788	04/25/2001	Per-Olof Larsson	PL9824	3855

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AMERSHAM BIOSCIENCES
PATENT DEPARTMENT
800 CENTENNIAL AVENUE
PISCATAWAY, NJ 08855

EXAMINER

VO, HAI

ART UNIT	PAPER NUMBER
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1771

DATE MAILED: 02/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/763,788

Applicant(s)

LARSSON ET AL.

Examiner

Hai Vo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6-12 and 17-32 is/are pending in the application.
- 4a) Of the above claim(s) 20-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6-12,17-19,31 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

1. All of the art rejections set forth in the 03/03/2004 Examiner's answer are maintained.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3, 4, 6-12, 17-19, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/19115 in view of Lihme et al (US 5,866,006).

In light of the specification (page 2, lines 18-21), the recitation "with exception of the case that the composite contains an electrically monolithic secondary component which is intended to be, or is connected between two electrodes" means that the composite containing an electrically monolithic secondary component which is connected between two electrodes is completely excluded from the claim. WO'115 teaches a porous polysaccharide having a network of two continuous phases, an aqueous polysaccharide phase and an organic phase, wherein the aqueous polysaccharide phase includes small diameter pores which are interconnected to give flow passages through the gel, and the organic phase is the superpore-forming phase comprising large diameter flow through pores (abstract). WO'115 discloses the polysaccharide comprising superpores in the range of 5 to 100 microns and micropores in the range of 30 to

500 Angstroms (page 3), meeting the specific ranges disclosed at page 1, lines 10-14 of Applicant's specification. WO'115 does not specially disclose the super-porous polysaccharide containing the gel phase with micropores outside the superpores. However, the pore arrangement would inherently be present since the WO'115 is using the same materials and the same mixing technique to prepare the porous material as Applicant. WO'115 discloses the polysaccharide gels in the form of discrete particles or a packed bed of agarose (examples 3, 5 and 7). WO'115 is silent as to the secondary component of the composite material. Lihme discloses the use of conglomerating agents in combination with polysaccharide in chromatographic procedures for binding, entrapping or carrying the polysaccharide (column 21, line 1 to column 22, line 1-60). Lihme discloses agarose as a conglomerating agent (column 21, lines 18-20). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a conglomerating agent as the secondary component of the porous material in WO'115 motivated by the desire to bind, entrap or carry the polysaccharides, which is important to the expectation of successfully practicing the invention of WO'115, thus suggesting the modification.

With regard to claims 3-5, since the conglomerate of Lihme acts as the filler and is mixed with the super-porous material of WO'115, it is the examiner's position that the conglomerate would be substantially inherently present anywhere in the matrix, i.e., outside the super-pores but inside the main

component's gel phase or in the super-pores of the main component or present in both the super-pores and in the gel-phase of the main-component.

With regard to claims 6-8, and 10, WO'115 discloses the super-porous material being coupled with various ligands (examples 8, 9 and 12).

With regard to claim 9, Lihme discloses the ligand being coupled with the conglomerate (column 18, lines 39-58). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to couple the ligand with the conglomerate motivated by the desire to keep the desired functions of the active polysaccharides intact before use.

With regard to claim 11, WO'115 discloses the super-porous material having the macropores with an average pore diameter in the gel phase from 5 to 100 microns (page 4). Lihme teaches the conglomerate having the pore size from 50-500 microns (column 14, line 53). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a conglomerate having the average pore size greater than that of the macropore in the gel phase of the main component motivated by the desire to control the flow rate of the separation.

With regard to claims 17-19, Lihme reads on the claim limitations (column 8, line 62 et seq.). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the composite material of WO'115 as modified by Lihme for variety applications as set forth in the claims because such is a, desirable, excellent solid phase matrix for use in

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variety applications and Lihme provides details to practice the invention of WO'115.

4. Claims 1, 3, 4, 6-12 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/19115 in view of Schaeffer et al (US 4,111,838).

WO'115 teaches a porous polysaccharide having a net work of two continuous phases, an aqueous polysaccharide phase and an organic phase, wherein the aqueous polysaccharide phase includes small diameter pores which are interconnected to give flow passages through the gel, and the organic phase is the superpore-forming phase comprising large diameter flow through pores (abstract). WO'115 discloses the polysaccharide comprising superpores in the range of 5 to 100 microns and micropores in the range of 30 to 500 Angstroms (page 3), meeting the specific ranges disclosed at page 1, lines 10-14 of Applicant's specification. WO'115 does not specially disclose the super-porous polysaccharide containing the gel phase with micropores outside the superpores. However, the pore arrangement would inherently be present since the WO'115 is using the same materials and the same mixing technique to prepare the porous material as Applicant. WO'115 discloses the polysaccharide gels in the form of discrete particles or a packed bed of agarose (examples 3, 5 and 7). WO'115 is silent as to the secondary component of the composite material. Schaeffer discloses a chromatographic material comprising an inorganic support-polysaccharide particle matrix. The matrix comprises an inorganic support that has a high surface density of hydroxyl groups and covalently attached to

polysaccharide particles (abstract). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ an inorganic support as the secondary component of the porous material in WO'115 motivated by the desire to bind, or carry the polysaccharides, which is important to the expectation of successfully practicing the invention of WO'115, thus suggesting the modification.

With regard to claims 3-5, since the inorganic support of Schaeffer is mixed with the super-porous material of WO'115, it is the examiner's position that the inorganic support would be substantially inherently present anywhere in the matrix, i.e., outside the super-pores but inside the main component's gel phase or in the super-pores of the main component or present in both the super-pores and in the gel-phase of the main-component.

With regard to claims 6-8, and 10, WO'115 discloses the super-porous material being coupled with various ligands (examples 8, 9 and 12).

With regard to claim 9, Schaeffer discloses the ligand being coupled with the inorganic support to control the multipoint attachments of the proteins (column 4, lines 3-30). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to couple the ligand with the inorganic support motivated by the desire to control the multipoint attachments of the proteins.

With regard to claim 11, WO'115 discloses the super-porous material having the macropores with an average pore diameter in the gel phase from 5 to

100 microns (page 4). Schaeffer teaches the inorganic support having the pore size from 100-1000 microns (column 3, line 56). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ an inorganic support having the average pore size greater than that of the macropore in the gel phase of the main component motivated by the desire to control the flow rate of the separation.

5. Claims 1, 3, 4, 6-12, 18 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/19115 in view of Manganaro et al (US 5,155,144).

WO'115 teaches a porous polysaccharide having a net work of two continuous phases, an aqueous polysaccharide phase and an organic phase, wherein the aqueous polysaccharide phase includes small diameter pores which are interconnected to give flow passages through the gel, and the organic phase is the superpore-forming phase comprising large diameter flow through pores (abstract). WO'115 discloses the polysaccharide comprising superpores in the range of 5 to 100 microns and micropores in the range of 30 to 500 Angstroms (page 3), meeting the specific ranges disclosed at page 1, lines 10-14 of Applicant's specification. WO'115 does not specially disclose the super-porous polysaccharide containing the gel phase with micropores outside the superpores. However, the pore arrangement would inherently be present since the WO'115 is using the same materials and the same mixing technique to prepare the porous material as Applicant. WO'115 discloses the polysaccharide gels in the form of discrete particles or a packed bed of agarose (examples 3, 5 and 7). WO'115 is

silent as to the secondary component of the composite material. Manganaro discloses that the microporous sheet for use in chromatography apparatus comprises a polymeric matrix including polyvinyl chloride beads and active polysaccharide (abstract, column 2, lines 65-67). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ polyvinyl chloride beads as the secondary component of the porous material in WO'115 motivated by the desire to bind the active polysaccharides, which is important to the expectation of successfully practicing the invention of WO'115, thus suggesting the modification.

With regard to claims 3-5, since the polyvinyl chloride beads of Manganaro is mixed with the super-porous material of WO'115, it is the examiner's position that the polyvinyl chloride beads would be substantially inherently present anywhere in the matrix, i.e., outside the super-pores but inside the main component's gel phase or in the super-pores of the main component or present in both the super-pores and in the gel-phase of the main-component.

With regard to claims 6-8, and 10, WO'115 discloses the super-porous material being coupled with various ligands (examples 8, 9 and 12).

With regard to claim 9, Manganaro discloses the porous sheet being capable of selectively binding targeted biological materials via ligand binding sites to keep the desired functions of the active polysaccharide intact before use (column 3, lines 25-40). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to couple the ligand

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with the polyvinyl chloride beads motivated by the desire to keep the desired functions of the active substance intact or may be reestablished before use.

With regard to claim 11, WO'115 discloses the super-porous material having the macropores with an average pore diameter in the gel phase form 5 to 100 microns (page 4). Manganaro teaches the polyvinyl chloride beads having the pore size of 140 microns (column 12, line 2). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ an inorganic support having the average pore size greater than that of the macropore in the gel phase of the main component motivated by the desire to control the flow rate of the separation.

With regard to claim 18, WO'115 discloses the super-porous material being used in an affinity chromatography and a bioreactor (column 2, lines 55-62).

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hai Vo whose telephone number is (571) 272-1485. The examiner can normally be reached on Monday through Friday, from 6:00 to 2:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on (571) 272-1478. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

HV



HAI VO
PRIMARY EXAMINER